

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,
ex. rel. DOUGLAS HAY, JAY
STAFFORD and TRACY STEIN

Plaintiff

v.

SCHERING-PLOUGH CORPORATION

Defendant

FILED
U.S. District Court
District of Massachusetts
Date 10-14-05
By Debby Clark

Civil Action
No. 01-11923-MLW

Filed Under Seal

UNITED STATES' STATUS REPORT REGARDING SETTLEMENT

As previously reported, the United States and Schering Plough Corporation reached an agreement in principle to settle certain issues raised in this case, and certain issues not part of this matter, on July 27, 2005. Thereafter, on August 12, 2005, the undersigned filed an affidavit providing a brief overview of the investigation and process required to bring this settlement to completion. Since the last status report, the government has diligently worked with the affected federal agencies, the 50 state Medicaid Fraud Control units through their negotiating team, and the relators to attempt to bring this settlement to successful completion. Two matters have slowed down the finalization process and necessitated the instant request for an additional extension of the seal- one involving the relators, and one involving the states.

Relators

The three relators in this case were sales representatives at Schering during the relevant period between 1999 and 2003. Many of their allegations are based on personal knowledge of

off-label sales and marketing practices, and payments to physicians to induce prescription of certain drugs as described in their complaint. As indicated previously, relators have certain rights under the False Claims Act, including to object to the proposed settlement if they believe it is not “fair, adequate, and reasonable.” See, 31 U.S.C. § 3730. If the relators ultimately disagree with the proposed settlement, the government will seek a decision from the Court whether the proposed settlement of the civil claims in this action that are being resolved by the proposed settlement are fair, adequate and reasonable.

The government has discussed with relators and their counsel why the government believes the settlement is appropriate. Two of the relators, Tracy Stein and Jay Stafford, are considering that information, have not yet determined their position on whether the settlement is fair, adequate and reasonable, and seek to meet further with the government to discuss those issues. One of the relators, Douglas Hay, has informed the government that he objects to the settlement as fair, adequate and reasonable, and seeks to meet further with the government to discuss his objections. Additional time is needed to complete those discussions, to determine the final positions of each of the relators, and to see whether there is an impasse. The government has requested dates from the relators to complete those discussions, and will advise the Court as soon as it determines whether further discussions are unlikely to resolve the relators’ issues and if a decision by the Court is necessary.

States

An experienced negotiating team for the state Medicaid Fraud Control Units has been assigned to this matter because of its complexity, including the involvement of multiple interested groups from various states such as consumer fraud divisions, as well as the Medicaid

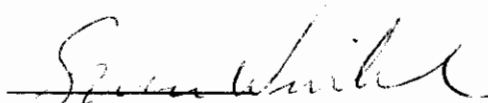
agencies. The attorneys on the state negotiating team have been largely unavailable to work on this matter over the past month. One of the major matters on which part of state negotiating team has been working is another major complex global criminal and civil health care fraud settlement in the District of Massachusetts involving Serono Laboratories, Inc., which will total \$704 million in fines and damages.¹ That settlement in principle was reached prior to this one, and the U.S. Attorney's Office has been attempting to get both done as quickly as possible. Like this settlement with Schering, the Serono settlement was very complex, involving multiple issues and affected agencies, and involved tremendous time from the state team to get all of the state issues resolved. The Serono papers are expected to be filed on Monday morning, October 17, 2005, with an announcement shortly thereafter. The government expects that with the anticipated resolution of the Serono matter, the state team will be in a position to devote its time and attention to the instant case.

The parties are working diligently to attempt to reach a successful completion of the proposed resolution. The government will advise the Court as soon as possible on the relator issue, and if an impasse is reached, seek a determination from the Court of whether the proposed civil settlement of the allegations that are part of the relators' complaint is fair, adequate and reasonable.

¹The Serono resolution involves a similarly sized investigation of a national pharmaceutical company – and will result in criminal charges and civil liability in connection with a drug, Serostim, used in treating AIDs wasting, which is a leading cause of death for AIDs patients. AIDs wasting was dramatically reduced with the advent of protease inhibitor drugs which entered the market about the time Serono received FDA approval for Serostim, and the demand for Serostim plummeted. Serono engaged in various illegal sales and marketing behavior to retain their market, including introduction of adulterated software into the marketplace to attempt to create a false perception of need for the use of Serostim, and paying kickbacks to physicians to obtain prescriptions for Serostim.

Respectfully submitted,

MICHAEL J. SULLIVAN
United States Attorney

A handwritten signature in cursive script, appearing to read "Susan Winkler", written over a horizontal line.

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